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EXAMINER
GODDARD, LAURA B

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 09/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/079,954	DURST ET AL.	
	Examiner	Art Unit	
	Laura B. Goddard, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *51-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *51-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

S.O.O

DETAILED ACTION

1. The Election filed October 29, 2004 in response to the Office Action of September 13, 2004 is acknowledged and has been entered. Applicants elected Group IV drawn to a kit, antibodies and antibody fragments without traverse. Applicants cancelled claims 38 and 46-50 and added claims 51-57 drawn to the elected invention. Claims 51-57 are currently under prosecution.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 51 is indefinite because it recites the term "**agent**." This renders the claim indefinite because the term **"agent"** is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The specification does not define the term agent nor does it give a limiting example of what an agent may consist of. Given the above reasons, the metes and bounds of the claims cannot be determined.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 51-57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. THIS IS A WRITTEN DECRIPTION REJECTION.

The claims are drawn to an agent or an antibody and a kit comprising an agent or an antibody that is specific for a polypeptide characteristic of early or late passages of HPV-immortalized cells. The specification only discloses the cDNAs C4.8 and C21.7 or SEQ ID NOs:1 and 2 as RNA or DNA detected and associated with the late passages of HPV-immortalized cells. The specification does not disclose agents or antibodies that are specific to any other polypeptides characteristic of early or late passages of HPV-immortalized cells as broadly encompassed in the claims.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. There is no identification of any particular portion of the structure that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Drawn to DNA arts, the findings in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) and Enzo Biochem, Inc. V. Gen-Probe Inc. are relevant to the instant claims. The Federal Circuit addressed the application of the written description requirement to DNA-related inventions in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). The court stated that " [a] written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name', of the claimed subject matter sufficient to distinguish it from other materials. " Id. At 1567, 43 USPQ2d at 1405. The court also stated that:

> a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA" without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is.

Id. At 1568, 43 USPQ2d at 1406. The court concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id.

Finally, the court addressed the manner by which a genus of cDNAs might be described. "A description of a genus of cDNAs may be achieved by means of a

recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." Id.

The Federal Circuit has recently clarified that a DNA molecule can be adequately described without disclosing its complete structure. See Enzo Biochem, Inc. V. Gen-Probe Inc., 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). The Enzo court adopted the standard that "the written description requirement can be met by show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ....i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." Id. At 1324, 63 USPQ2d at 1613 (emphasis omitted, bracketed material in original).

The inventions at issue in Lilly and Enzo were DNA constructs per se, the holdings of those cases are also applicable to claims such as those at issue here. Thus, the instant specification may provide an adequate written description of the agent or antibody that is specifically for a polypeptide characteristic of early or late passages of HPV-immortalized cells, per Lilly by structurally describing representative polypeptides that the antibody specifically binds or by describing "structural features common to the members of the genus, which features constitute a substantial portion of the genus." Alternatively, per Enzo, the specification can show that the claimed invention is complete "by disclosure of sufficiently detailed, relevant identifying

characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics."

In this case, the specification does not directly describe a polypeptide characteristic of early or late passages of HPV-immortalized cells to which the claimed agent or antibody is specific for in a manner that satisfies either the Lilly or Enzo standards. Although the specification discloses the cDNAs C4.8 and C21.7 or SEQ ID NOs:1 and 2, this does not provide a description of the broadly claimed polypeptides characteristic of early or late passages of HPV-immortalized cells to which an agent or antibody is specific for that would satisfy the standard set out in Enzo because the specification provides no functional characteristics coupled to structural features.

Further, the specification also fails to describe a polypeptide characteristic of early or late passages of HPV-immortalized cells that an agent or antibody is specific for by the test set out in Lilly because the specification describes only a the cDNAs C4.8 and C21.7 or SEQ ID NOs:1 and 2. Therefore it necessarily fails to describe a representative number of such species.

Thus, the specification does not provide an adequate written description of a polypeptide characteristic of early or late passages of HPV-immortalized cells to which the claimed agent or antibody is specific for that is required to practice the claimed invention. Since the specification fails to adequately describe the product to which the claimed agent or antibody is specific for, it also fails to adequately describe the antibody and agent.

Further, the following teaching of the court as set out in Noelle also clearly applies to the instant claimed invention. The court teaches as follows: "Noelle did not provide sufficient support for the claims to the human CD40CR antibody in his '480 application because Noelle failed to disclose the structural elements of human CD40CR antibody or antigen in his earlier '799 application. Noelle argues that because antibodies are defined by their binding affinity to antigens, not their physical structure, he sufficiently described human CD40CR antibody by stating that it binds to human CD40CR antigen. Noelle cites Enzo Biochem II for this proposition. This argument fails, however, because Noelle did not sufficiently describe the human CD40CR antigen at the time of the filing of the '799 patent application. In fact, Noelle only described the mouse antigen when he claimed the mouse, human, and genus forms of CD40CR antibodies by citing to the ATCC number of the hybridoma secreting the mouse CD40CR antibody. If Noelle had sufficiently described the human form of CD40CR antigen, he could have claimed its antibody by simply stating its binding affinity for the "fully characterized" antigen. Noelle did not describe human CD40CR antigen. Therefore, Noelle attempted to define an unknown by its binding affinity to another unknown. As a result, Noelle's claims to human forms of CD40CR antibody found in his '480 application cannot gain the benefit of the earlier filing date of his '799 patent application. Moreover, Noelle cannot claim the genus form of CD40CR antibody by simply describing mouse CD40CR antigen". *Randolph J. Noelle v Seth Lederman, Leonard Chess and Michael J. Yellin* (CAFC, 02-1187, 1/20/2004).

In the instant application, the specification only discloses the cDNAs C4.8 and C21.7 or SEQ ID NOs:1 and 2 to which the claimed antibody or agent is specific for. The instant application does not however fully describe a polypeptide characteristic of early or late passages of HPV-immortalized cells.

Since the instant application does not fully describe the genus of antigen to which the claimed antibody or agent is specific for, the instant application cannot claim the genus form of antibody or agent. Thus, the specification fails to describe the claimed agent or antibody and kit comprising the agent or antibody, by the test set out in the example of Noelle.

Note: If applicant were to overcome the preceding rejection (s) under 35 U.S.C. 112, first paragraph, the following claims would still be rejected under 35 U.S.C. 112, first paragraph, scope of enablement:

4. Claims 51-57 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an antibody and a kit comprising an antibody that specifically binds to SEQ ID NOs:1 or 2, does not reasonably provide enablement for an agent or antibody that is specific for a polypeptide characteristic of early or late passages of HPV-immortalized cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The claims are drawn to an agent or an antibody and a kit comprising an agent or an antibody that is specific for a polypeptide characteristic of early or late passages of

HPV-immortalized cells. This means the claims are drawn to an agent or antibody that is specific for a multitude of polypeptides wherein the polypeptide amino acid sequences are unknown, the structures of the polypeptides are unknown, and the structure of the antibody or agent is unknown. Thus, Applicant is claiming an unknown antibody or agent by referencing an unknown protein.

The specification only discloses the cDNAs C4.8 and C21.7 or SEQ ID NOs:1 and 2 as RNA or DNA detected and associated with the late passages of HPV-immortalized cells. The specification does not disclose agents or antibodies that are specific to any other polypeptides characteristic of early or late passages of HPV-immortalized cells as broadly encompassed in the claims.

One cannot extrapolate the teaching of the specification to the scope of the claims because the claims as written are drawn to an agent or an antibody that is specific for a polypeptide characteristic of early or late passages of HPV-immortalized cells wherein the polypeptide amino acid sequence are unknown, the structures of the polypeptides are unknown, and the structure of the antibody or agent is unknown. Bowie et al (Science, 1990, 247:1306-1310) teach that an amino acid sequence encodes a message that determines the shape of a protein and determines the ability of said protein to fold into unique three-dimensional structures that allows them to function. Bowie et al further teach that certain positions in the sequence are critical to the three dimensional structure/function relationship and these regions can tolerate only conservative substitutions or no substitutions (p. 1306, cols 1 and 2). Clearly, the three dimensional structure of a protein is critical to the production of antibodies given the

teaching of Herbert et al (The Dictionary of Immunology, Academic Press, 3rd Edition, London, 1985, pages 58-59). Herbert et al who specifically teach that an epitope is the region on an antigen molecule to which antibody specifically binds. B cell epitopes on protein antigens are of variable size comprising up to about 20 amino acids. Antibodies bind in a more or less exact three-dimensional fit with an epitope. This may be formed from residues on different regions of a protein antigen molecule which, in the native state, are closely apposed due to protein folding. Thus the three-dimensional structure of the protein molecule may be essential for antibody binding. (p. 58). However, neither the specification nor the art of record provide teachings that provide information about the structure of the broadly claimed polypeptides required for the specific binding of antibodies. This information appears to be critical because the art recognizes (see Bowie above) that it is the protein sequence that determines the three dimensional shape of a protein and Herbert et al specifically state that antibodies bind in a more or less exact three dimensional fit and suggests that the three-dimensional structure of the protein molecule may be essential for antibody binding. Thus, in the absence of guidance in the specification, the effects of the alterations of amino acids on the structure of the undefined proteins to which the antibody is claimed to be binding, and thus the antibodies that will be produced from and bind to that structure, cannot be predicted and one could not determine how to make the claimed invention because one would not be able to predictably recognize or identify the antibodies encompasses by the claims.

One of skill in the art would not be able to anticipate what antibody or agent would be specific for a polypeptide characteristic of early or late passages of HPV-immortalized cells. Given the lack of guidance in the specification and the unpredictability in the art, one of skill in the art would be subject to undue experimentation in order to practice the claimed invention.

Note: If applicant were to overcome the preceding rejection (s) under 35 U.S.C. 112, first paragraph, the following claims would still be rejected under 35 U.S.C. 112, first paragraph, enablement:

5. Claims 51 and 57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to a kit comprising agents to detect presence/absence and/or the level of a polypeptide characteristic of early or late passages of HPV immortalized cells (claim 51), wherein the agent is an antibody specific for a polypeptide characteristic of early of late passages of HPV-immortalized cells (claim 57).

The specification discloses two DNA sequences (c4.8 and C21.7) from RNA that were isolated from early and late passages of HPV-immortalized cell line HPK-IA (Example 1, p. 5-7). Example 2 of the specification (p. 8) discloses labeled cDNAs C4.8

and C21.7 hybridized and reacted "much more strongly" with the RNA from the late passages of the HPK-IA cells than with the early passages (no data shown). Example 2 of the specification (p. 8) also discloses RNA hybridization probes produced from C4.8 and C21.7 which had stronger hybridization to cervical carcinoma than to normal epithelial tissue (no data shown). The specification teaches the detection of RNA characteristic of late passages of HPV immortalized cells. However, other than a hypothesis, there is nothing in the specification that suggests that a polypeptide is expressed from the isolated RNA or DNA as associated with early or late passage HPV-immortalized cells, or that a polypeptide is detected in early or late passage HPV-immortalized cells and is a predictable target for diagnosing or indicative of cervical lesions using agents or antibodies specific for the polypeptide.

Further, those of skill in the art recognize that increased expression of a particular nucleic acid specific for a tissue type, does not necessarily correlate nor predict equivalent levels of polypeptide expression. There are many steps in the pathway leading from DNA to protein, and all of them can, in principle, be regulated. For example, Alberts et al. (Molecular Biology of the Cell, 3rd edition, 1994, page 465) illustrate post-transcriptional regulation of ferritin wherein the translation of ferritin mRNA into ferritin polypeptide is blocked during periods of iron starvation. Likewise, if excess iron is available, the transferrin receptor mRNA is degraded and no transferin receptor polypeptide is translated. Lewin, B. also teaches (Genes VI, Oxford University Press, Inc., NY, Chapter 29, 1997) that a major control point for genes exists during the initiation of transcription by the interaction of the RNA polymerase with its promoter.

Concurring with Alberts et al., Lewin further acknowledges downstream control of gene expression since translation of mRNA in the cytoplasm is also a point of control. Also, with regards to tumor-associated antigens, Fu et al (EMBO Journal, 1996, Vol. 15, pp. 4392-4401) teach that levels of p53 protein expression do not correlate with levels of p53 mRNA levels in blast cells taken from patients with acute myelogenous leukemia, said patients being without mutations in the p53 gene. Furthermore, Mallampalli et al. (Biochem. J. Vol. 318, 1996, pages 333-341) teach that the glucocorticoid, betamethasone, increased mRNA expression of cholinephosphate cytidylyltransferase (CT) as determined by RT-PCR and Southern analysis, but did not alter the levels of the CT enzyme as assayed by Western blotting (abstract, and page 339, 2nd column, 2nd paragraph). Finally, Lewin acknowledges that control of gene expression can occur at multiple stages and that production of RNA cannot inevitably be equated with production of protein. Thus, the predictability of protein translation and its possible utility as a diagnostic are not necessarily contingent on the levels of mRNA expression due to the multitude of homeostatic factors affecting transcription and translation. Thus, in the absence of any correlation between the claimed polypeptide(s) with any known disease or disorder, any information obtained from various expression profiles in both normal and diseased tissue only serves as the basis for further research on the observation itself. Therefore, absent evidence of the protein's expression including the correlation to cervical cancer, one of skill in the art would not be able to predictably use the antigen in any diagnostic setting without undue experimentation. Therefore, absent evidence of the protein's expression one of skill in the art would not be able to predict the presence

of a polypeptide characteristic of early or late passages of HPV-immortalized cells for diagnostic purposes.

Further, it is noted that MPEP 2164.03 teaches that "the amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability of the art. In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). The amount of guidance or direction refers to that information in the application, as originally filed, that teaches exactly how to make or use the invention. The more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to explicitly stated in the specification. In contrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as how to make and use the invention in order to be enabling."

Given the unpredictability of identification of any polypeptide characteristic of early or late passages of HPV-immortalized cells, the lack of adequate disclosure in the specification, and in view of the complex nature of the claimed invention, and little is known in the art about the claimed invention, one of skill in the art would be forced into undue experimentation to practice the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 52-54 rejected under 35 U.S.C. 102(b) as being anticipated by Selvey et al (J Virol Methods, 1992, 37:119-27).

The claims are drawn to an antibody specific for a polypeptide characteristic of early or late passage HPV immortalized cells wherein the antibody is polyclonal or monoclonal.

Selvey et al teach polyclonal and monoclonal antibodies directed toward an HPV E7 protein, a protein well known in the art and characteristic of early or late passage of HPV immortalized cells (see abstract and p. 120).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 51-54, and 57 rejected under 35 U.S.C. 103(a) as being unpatentable over Selvey et al (J Virol Methods, 1992, 37:119-27), in view of Oncogene Science Catalogue (1992, p 13).

It is noted that the preamble recitation of a kit "useful for diagnosis of cervical lesions and the evaluation of the potential progression potential of cervical lesions" is

merely suggestive of an intended use and is not given weight for purposes of comparing the claims with the prior art. The claims read on the active ingredients *per se*, which is an agent/antibody or a kit comprising an agent/antibody that detects a polypeptide.

The claims are drawn to a kit comprising a first agent to detect presence/absence and/or the level of a polypeptide characteristic of early or late passages of HPV immortalized cells and a second agent useful in diagnosis of cervical lesions (claim 51), wherein the first agent is an antibody specific for a polypeptide characteristic of early of late passages of HPV-immortalized cells (claim 57), and a polyclonal or monoclonal antibody that is specific for a polypeptide characteristic of early or late passages of HPV immortalized cells (52-54).

Selvey et al teach polyclonal and monoclonal antibodies directed toward an HPV E7 protein, a protein well known in the art and characteristic of early or late passage of HPV immortalized cells (see abstract and p. 120). The reference teaches an ELISA capture assay for the HPV E7 protein, an assay that uses an antibody to detect E7 protein and a peroxidase label to detect the antibody-protein complex. The reference teaches that the assay of E7 protein may play a role in the detection of HPV-induced cervical lesions with malignant potential (abstract and p. 126). Selvey et al do not teach a kit comprising the antibody and label for detection.

Oncogene Science sell a kit comprising an antibody for HPV E6 protein (p. 13), another protein well known in the art and characteristic of early or late passage of HPV immortalized cells (see p. 119 of Selvey et al).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to substitute the E7 antibody of Selvey et al for the E6 antibody of Oncogene Science to produce a kit for assay of E7 to be used in the assay method of Selvey et al because Oncogene Science provides commercially, readily available antibodies for the detection of proteins well known in the art and characteristic of early or late passage of HPV immortalized cells. One would have been motivated to substitute the E7 antibody of Selvey et al into the kit of Oncogene Science because the antibody would allow detection of a polypeptide known to be characteristic of early or late passage of HPV immortalized cells in the ELISA method if Selvey et al and, subsequently, detection of HPV-induced cervical lesions, and provide a standard kit that would enhance the probability of the reproducibility and efficiency of the detection process.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura B. Goddard, Ph.D. whose telephone number is (571) 272-8788. The examiner can normally be reached on 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Laura B Goddard, Ph.D.
Examiner
Art Unit 1642

SUSAN UNGAR, PH.D
PRIMARY EXAMINER